K072381

510(k) SUMMARY

October 11, 2007

CONTACT:
Richard Domanik, Ph.D.
CytoCore, Inc.
414 North Orleans
Chicago, IL 60610

JAN 30 2008

NAME OF DEVICES:

Trade Name:	*SoftPAP*™ Collector
Common Names/Descriptions:	Cervical Cytology Specimen Collector
Classification Name:	Spatula, cervical, cytological
Classification Product Code:	HHT

PREDICATE DEVICE:
CytoCore e2™ Collector, K013285

DEVICE DESCRIPTION:

Intended Use: For the collection of cervical cytology specimens for Pap test analysis. The *SoftPAP*™ Cervical Sample Collector should not be used after the first 10 weeks of gestation in pregnant patients.

Product Description: The CytoCore, Inc. *SoftPAP*™ Collector is a multi-component assembly for the collection of exfoliated cervical epithelial cells. Its major components are a disposable Balloon assembly (Balloon and rod), and a reusable Handle. The Balloon provides the conformal surface upon which the cells are collected. The Handle provides a means of manipulating and expanding the Balloon during the sampling process. The Balloon inflates against the cervix and conformally contacts the entire areas to be sampled, namely the ectocervical, the transformation zone, and the endocervical surfaces.

SUBSTANTIAL EQUIVALENCE:
This Special 510(k) was submitted to describe modifications to the device for physician ease-of-use and manufacturability issues. The modifications did not affect the Intended Use, Indications for Use, balloon material, balloon inflation profile, or any components that come in contact with the patient or patient cells. Therefore, the modified device is substantially equivalent to the original e^2 Collector™ which was FDA-cleared on May 31, 2002 (K013258). The substantive differences between the e^2™ and *SoftPAP*™ Collectors are summarized in the following table.

Differences between the e2 and *SoftPAP* Collectors	
e^2 Collector	***SoftPAP* Collector**
Single integrated unit	Separate reusable handle and single use collection device
Vacuum used to collapse the collector balloon	A mechanism in the handle mechanically collapses the collector balloon
A syringe is used to directly inflate the collector balloon	A syringe is used to inject air into a reservoir in the handle. The reservoir is discharged into the collector balloon by pressing a button on the handle
The collector balloon is deflated via a combination of a controlled leak and a separate push valve	The collector balloon is automatically deflated upon releasing the button on the handle
No sanitary cover over the handle	A disposable sanitary cover that minimizes the potential for handle contamination is part of each collector.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JAN 30 2008

Richard A. Domanik, Ph.D.
President
CytoCore, Inc.
414 North Orleans, Suite 502
CHICAGO IL 60610

Re: K072381
Trade/Device Name: CytoCore *Soft*PAP™ Collector
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: HHT
Dated: January 10, 2008
Received: January 11, 2008

Dear Dr. Domanik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K072381

Device Name: CytoCore *SoftPAP*™ Collector

Indication For Use:

For the collection of cervical cytology specimens for Pap test analysis. The *SoftPAP*™ Cervical Sample Collector should not be used after the first 10 weeks of gestation in pregnant patients.

Prescription Use __X____ And/Or Over the Counter Use _____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

Division Sign-Off
Office of Device Evaluation

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